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Hon. George A. O'Toole
United States District Court
John Joseph Moakley United States Courthouse
1 Courthouse Way
Boston, MA 02210

Re: *United States v. Stryker Biotech, LLC et al.*, Case No. 09-CR-10330-GAO

Dear Judge O'Toole:

I write on behalf of the five Defendants in the above-captioned case, who hereby jointly submit the attached opinion of the United States Supreme Court in *Sorrell v. IMS Health, Inc.*, 564 U.S. ____ (June 23, 2011), as supplemental authority in support of their Motion to Dismiss Counts Seven through Fourteen (First Amendment Motion) (Docket # 65). The *Sorrell* opinion, written by Justice Anthony Kennedy, provides new precedent on several of the principal issues implicated by Defendants' Motion to Dismiss, including the First Amendment protections afforded to speech in aid of pharmaceutical marketing, the heightened scrutiny standard that applies to content- and speaker-based restrictions on such speech, and the particular value to physicians and patients of a free flow of information on medical and scientific topics.

Sorrell involved a challenge to a provision of the Vermont Prescription Confidentiality Law, Vt. Stat. Ann., Tit. 18, § 4631 (Supp. 2010), which prohibited pharmacies, absent consent, from selling or disclosing to pharmaceutical manufacturers any pharmacy records that revealed the prescribing practices of individual physicians, and similarly prohibited pharmaceutical manufacturers from using that information in marketing their products to physicians. At the same time, the Vermont statute freely allowed pharmacy records to be disclosed and used for a variety of non-marketing purposes—a situation analogous to the misbranding regulations challenged in Defendants' Motion to Dismiss, which criminalize discussion of “off-label” medical information by manufacturers (and only manufacturers) that is entirely lawful when offered by other speakers. Vermont argued that heightened scrutiny was unwarranted because its law was merely a commercial regulation, and further justified the statute as necessary to protect medical privacy and to advance the public policy goals of lowering health care costs and promoting public health.

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The *Sorrell* Court firmly rejected Vermont's characterization of the law as a commercial regulation with an incidental effect on speech:

The statute[’s restrictions] thus disfavor[] marketing, that is, speech with a particular content. More than that, the statute disfavors specific speakers, namely pharmaceutical manufacturers . . . even though the information may be purchased or acquired by other speakers with diverse purposes and viewpoints. . . . Vermont’s law thus has the effect of preventing [manufacturers]—and only [manufacturers]—from communicating with physicians in an effective and informative manner.

Sorrell, 564 U.S., *slip op.* at 8-9. Affirming that “[s]peech in aid of pharmaceutical marketing” is protected under the First Amendment, the Court made clear that because the Vermont law was “designed to impose a specific, content-based burden on protected expression,” heightened judicial scrutiny was warranted. *Id.* at 1, 9.¹ The Court noted, however, that the Vermont statute still could not be justified under the lesser inquiry afforded commercial speech regulations, as set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), and the case’s outcome would be the same no matter which form of scrutiny was applied. *Sorrell*, 564 U.S., *slip op.* at 15-16.

Although it assumed that Vermont’s justifications for enacting the Prescription Confidentiality Law—medical privacy, improved public health, and reduced health care costs—were significant, the *Sorrell* Court held that the law was not sufficiently narrowly drawn to achieve these objectives, and that Vermont erred in pursuing its legislative goals “through the indirect means of restraining certain speech by certain speakers,” and without offering any explanation “why remedies other than content-based rules would be inadequate.” *Id.* at 20-22. Noting that pharmaceutical marketing is even “more benign and, many would say, beneficial” than other types of protected speech, the Court found that the public interest is better served by fewer restrictions on the free flow of commercial speech, particularly “in the fields of medicine and public health, where information can save lives.” *Id.* at 21, 11. The First Amendment’s presumption against content-based burdens on speech is all the stronger when the intended recipients of such speech, “in this case prescribing physicians, consist[] of ‘sophisticated and experienced’ consumers.” *Id.* at 22 (quoting *Edenfield v. Fane*, 507 U.S. 761, 775 (1993)). The *Sorrell* Court therefore held that the Prescription Confidentiality Law violated the First Amendment by burdening the speech of pharmaceutical manufacturers without adequate justification.

¹ Vermont also argued that its law did not regulate speech at all, merely access to information, a contention that the *Sorrell* Court also rejected: “An individual’s right to speak is implicated when information he or she possesses is subjected to ‘restraints on the way in which the information might be used’ or disseminated. *Sorrell*, 564 U.S., *slip op.* at 12-13 (quoting *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 32 (1984)). Guided by *Sorrell*, this Court similarly should reject the government’s suggestion that the misbranding regulations prohibit manufacturer conduct and not speech.

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Notably, *Sorrell* explicitly overturns two earlier First Circuit opinions upholding Maine and New Hampshire's similar statutes regulating pharmaceutical manufacturers' use of prescription records: *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010), and *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008). *Sorrell*, 564 U.S., *slip op.* at 6. Both *Mills* and *Ayotte* held that prohibitions on pharmaceutical manufacturers' marketing efforts regulated conduct and not speech, a holding that the Supreme Court now expressly rejects. *Mills*, 616 F.3d at 19; *Ayotte*, 550 F.3d at 53; *Sorrell*, 564 U.S., *slip op.* at 14-15. And *Sorrell* invalidates the holdings in *Mills* and *Ayotte* that pharmaceutical marketing is of less constitutional value than other forms of speech. *Compare Ayotte*, 550 F.3d at 54 ("[Such] information exchanges . . . are not, however, the sorts of exchanges valued by the Supreme Court's First Amendment jurisprudence. . . .") with *Sorrell*, 564 U.S., *slip op.* at 1 ("Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment .").

The "mixing instructions" challenged by Defendants in the instant case are, as quoted in Counts Seven through Fourteen of the Indictment, plain and unadorned directions for preparing OP-1 and Calstrux in combination. Nowhere in the challenged counts does the Indictment allege that the language of the mixing instructions was false or misleading. Similarly, Count Six of the Indictment charges Defendants with a dual-pronged criminal conspiracy in violation of 18 U.S.C. § 371. The "offense prong" of Count Six charges Defendants *only* with the offense of providing "written instructions" for preparing a mixture of Calstrux and OP-1, and again contains no allegation that the language of those instructions was false or misleading. Such instructions would be entirely lawful out of the mouth of any speaker other than Stryker Biotech and its employees, and in the wake of *Sorrell*, it is inconceivable that they could be classified as *per se* misleading or fraudulent simply because they were offered by a manufacturer. The Government has rightly conceded that it would have to prove beyond a reasonable doubt that the Defendants acted "with a 'fraud' based mental state" in order to successfully convict them of felony misbranding charges. Gov't Opp. to Def. Mot. to Dismiss, Dkt. #72, at 2. But *Sorrell* casts even graver doubt on the constitutional question of whether these informational exchanges can be, consistent with the First Amendment, criminally punished *at all*: Applying the logic of the opinion, there should not be any reason that manufacturers cannot engage in off-label discussions that are permissible by other speakers. If the defendants intended to deceive or defraud doctors, the Government would be free to charge them with other crimes as appropriate, but would be constitutionally prohibited from charging them with the offense of misbranding or, by extension, conspiracy to commit misbranding.²

By criminalizing all truthful, non-misleading speech by manufacturers about off-label uses of approved drugs and devices, the misbranding regulations impose impermissible content- and speaker-based burdens on First Amendment-protected expression. The regulations cannot

² To the extent that the Government has based the "defraud prong" of the conspiracy alleged in Count Six on Defendants' alleged provision of information on unapproved uses of Stryker Biotech products, *Sorrell* would counsel dismissal of that charge as well.

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withstand the heightened judicial scrutiny that *Sorrell* demands, and this Court should dismiss Counts Seven through Fourteen, as well as the “offense prong” of Count Six, on the grounds upon which Defendants previously have moved.

Respectfully submitted,

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BTO:cal

Attachment